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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,387	06/29/2000	BERND FABRY	H-3185-PCT/U	2050

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EXAMINER	
JIANG, SHAOJIA ANNA	
ART UNIT	**PAPER NUMBER**
1617	31

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,387	FABRY, BERND	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the decision of the Board of Patent Appeals and Interferences mailed September 15, 2004 that reverses the rejection of claims 11-30 made under 35 U.S.C. 103(a) of record, the rejection on appeal is withdrawn and therefore moot.

In view of **new prior art** which indicates nonpatentability of the appealed claims, and Applicant's admission regard the prior art in the specification at page 3 line 13-15, as pointed out in "Other Issues" in the decision of the Board of Patent Appeals and Interferences at page 8-10, PROSECUTION IS HEREBY REOPENED under 37 CFR 1.198 for the purpose of entering the new rejection. See MPEP § 1002.02(c) and MPEP § 1214.07 and 1214.04. A new ground of rejection(s) set forth below.

Currently, claims 11-30 are pending in this application.

The claims 11-30 are examined on the merits herein.

It is noted that this application is a 371 of PCT/EP98/07059 (filed November 14, 1998) which claims foreign priority to German 197 50 453.1 (filed November 5, 1997) under 35 U.S.C. 119(a)-(d). The copy of certified copy of the priority has been filed with the instant Application. It is noted German 197 50 453.1 is in Germany; no translation of said Germany application into English has been provided.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-18, 20-27, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939 of record), Miettinen et al. (EP 0594612B1 of record), and Hasegawa et al.(English translation of record) in view of Lee et al. ("Conjugated Linoleic Acid and atherosclerosis in rabbits", PTO-892) or Applicant's admission regard the prior art in the specification at page 4 line 13-15.

Jandacek discloses that phytosterols (synonymously phytostenols) have significant hypocholesterolemic activities (see col.1 lines 5-30), which meets the limitation in (i) (a) in claims 11 and 21 herein.

Jandacek also discloses that the compositions comprising phytosterols such as β–sitosterol (synonymously β-sitostenol) along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms (known to encompass double bonds) or glycerides of such fatty acids, in effective amounts from about 2.0 to about 6.0 wt.% and 0.5 to 15 wt.%, and/or combined with foodstuffs to be administered to the mammal, are useful for reducing serum cholesterol content in a mammal (see col.1 lines 5-30, col.2 lines 1-5, col.3 lines 27-28, col.4 lines 41-44, Table I, col.5 lines 17-31, Example I and claims 1, 3 and 6). The teachings of Jandacek meet the limitations, β-sitostenol and/or esters thereof recited in claims 12 and 22; the limitations, the carboxylic acid, R^1COOOH having from 6 to 18 carbon atoms in claims 13-16 and 22-26 herein, and combing foodstuff in claims 20 and 30.

Miettinen et al. teaches that β–sitosterol (β-sitostenol) and β–sitostanol and their fatty acid esters are known to be useful to lower serum cholesterol levels. See page 2 lines 5-7 and claim 1. This teaching meets the limitation in (i) (a) in claims 11-12 and 21-22 herein.

Miettinen et al. further teaches that usable fatty acids therein contain approx. 2-22 carbon atoms such as fatty acids in vegetable oil, i.e., rapeseed oil containing unsaturated fatty acids having from 2-22 carbon atoms (known to encompass double bonds). See page 3 lines 44-45 and Example 1 on page 4.

It is well known that many vegetable oils including rapeseed oil contain unsaturated fatty acids having one or more double bonds such as linoleic acid which has 18 carbons (see The Merck Index at page 5526, of record). Miettinen et al. teaches broadly the usefulness of fatty acid esters of β–sitosterol (β-sitostenol) and β–sitostanol containing approx. 2-22 carbon atoms including unsaturated fatty acid esters in the instant claimed method. This teaching meets the limitations in claims 13-16 and 22-26 herein.

Miettinen et al. further discloses that β-sitostenol fatty acid ester mixture in **combination** with rapeseed oil (containing unsaturated fatty acids having one or more double bonds such as linoleic acid, as active agents) decreased total cholesterol by 9.5% more and LDL cholesterol by 11.6% more than did rapeseed oil alone (see particularly page 4 lines 22-24). Thus, Miettinen et al. teach that the combination of phytostenol esters and fatty acids broadly including linoleic acid, is used in the instant claimed method.

Hasegawa et al. teaches that the particular fatty acid, linoleic acid, and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals. The testing results in Hasegawa et al. show that linoleic acid and sitosterol in abundance contained in the vegetable oils have hypocholesteremic effects (see Table 1-5 and Figure 3-4). See also abstract and the entire article. Thus, the teachings of Hasegawa et al. teach that the **combination** of linoleic acid and sitosterol is used in the instant claimed method.

The cited prior art herein does not expressly disclose the employment of conjugated linoleic acid (CLA), as a conjugated fatty acid, in combination with a phytosterol or phytosterol esters in methods of reducing serum cholesterol content, as recited in (i) (b) in the instant claims 11, 17, 21, 27.

Lee et al. discloses that conjugated linoleic acid (CLA) significantly lowers or reduces serum the LDL cholesterol by administering CLA in the effective amounts to rabbits (see abstract, Fig 1 and 3, "Results and discussion" at page 21-22).

Applicants admit and acknowledge that "[i]t is known of conjugated linoleic acid that it has a low hypocholesteremic action" in the specification at page 4 line 13-15.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ conjugated linoleic acid (CLA) in combination with a phytosterol or phytosterol esters in methods of reducing serum cholesterol content.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ CLA in combination with a phytosterol or phytosterol

esters in methods of reducing serum cholesterol content, since CLA is known to significantly reduce serum LDL cholesterol in animals.

Moreover, one of ordinary skill in the art would have reasonably expected that combining CLA and a phytostenol or of phytostenol esters of a fatty acid herein, all known useful for the same purpose in a composition to be administered would improve the therapeutic effect for reducing serum cholesterol content in a mammal. At least some additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) which renders the claims prima facie obvious.

Further, the motivation for the combination of phytostenol or its esters and fatty acids broadly including conjugated linoleic acid, employed in the instant claimed method, has been clearly provided by Miettinen et al. and/or Hasegawa et al. respectively.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 19, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939 of record), Miettinen et al. (EP 0594612B1), and Hasegawa et al. in view of Lee et al. or Applicant's admission regard the prior art in the specification at page 4 line 13-15 as applied to claims 11-18, 20-27, 30, further in view of Hidevgi (US 5,277,910, of record).

The same disclosures of Jandacek, Miettinen et al., and Hasegawa et al. have been discussed above. In particular, Jandacek discloses that the amount of phytosterols in the composition is from about 2.0 to about 6.0 wt.% and 0.5 to 15 wt.%, as pointed out above.

The cited prior art herein does not expressly the composition is in the form of gelatin capsules.

Hidvegi discloses a similar pharmaceutical composition for the same use, lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid formulated into gelatin capsules. See col.1 lines 59-65, col.2 line 37, col.3 line 38 and col.8 lines 18-28.

One having ordinary skill in the art at the time the invention was made would have been motivated to formulate the composition into gelatin capsules since the similar pharmaceutical composition for the same purpose, lowering the blood-lipid level, containing sitosterol and fatty acids such as linoleic acid, is known to be formulated into gelatin capsules according to Hidvegi. Formulation in various known forms is deemed within the knowledge and conventional skills in pharmaceutical art.

Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939 of record), Miettinen et al. (EP 0594612B1 of record), and Hasegawa et al.(English translation of record) in view of Pariza et al. (US 5,837,733, PTO-892), further in view of Hidevgi (US 5,277,910, of record).

The same disclosures of Jandacek, Miettinen et al., Hasegawa et al. and Hidvegi have been discussed in the 103(a) rejections above.

The cited prior art herein does not expressly disclose the employment of a conjugated fatty acid, e.g., conjugated linoleic acid (CLA), in lieu of linoleic acid (LA), in combination with a phytosterol or phytosterol esters in methods of reducing serum cholesterol content.

Pariza et al. discloses that conjugated linoleic acid (CLA) significantly lowers or reduces much more serum apolipoprotein B secretion in animals than linoleic acid (LA) does according to the testing results therein (see Fig 1, col.2 line 34-37; "Results" at col.4 line 65 to col.5 line 27). Apolipoprotein B secretion is known to associate or increase so-called "bad" cholesterols, VLDL and LDL cholesterols (see col.1 lines 17-26); thus CLA reduces "bad" cholesterols, VLDL and LDL via reducing apolipoprotein B secretion in the blood. Hence, Pariza et al. teaches that CLA is much more effective than LA in reducing serum "bad" cholesterols through reducing apolipoprotein B secretion in animals. Pariza et al. also disclose the administration of CLA in the effective amounts to an animal or mammal (see col.9 line 20-47 and claims 1-10).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ conjugated linoleic acid (CLA) in lieu of linoleic acid (LA) in the claimed methods of reducing serum cholesterol content.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ CLA in lieu of LA in the claimed methods of reducing

serum cholesterol content, since CLA is known to be much more effective than LA in reducing serum "bad" cholesterols through reducing apolipoprotein B secretion in animals.

Therefore, the property and benefit of CLA over LA in reducing serum "bad" cholesterols through reducing apolipoprotein B secretion in animals, have clearly provided the motivation of the claimed invention.

Moreover, one of ordinary skill in the art would have reasonably expected that combining a fatty acid such as CLA and a phytostenol or of phytostenol esters of a fatty acid herein, all known useful for the same purpose in a composition to be administered would improve the therapeutic effect for reducing serum cholesterol content in a mammal. At least some additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) which renders the claims prima facie obvious.

Further, the motivation for the combination of phytostenol esters and fatty acids broadly including linoleic acid and also including conjugated linoleic acid, employed in the instant claimed method, has been provided by Miettinen et al. and/or Hasegawa et al. respectively.

Furthermore, formulating the composition into gelatin capsules is deemed obvious since the similar pharmaceutical composition for the same purpose, lowering the blood-lipid level, containing sitosterol and fatty acids such as linoleic acid is known to be formulated into gelatin capsules according to Hidvegi.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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January 21, 2005

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